REMARKS

This is a full and timely response to the final Official Action mailed **November 15, 2006.** Reconsideration of the application in light of the following remarks is respectfully requested.

Claim Status:

No amendments are proposed by the present paper. Claims 1-25 are currently pending for further action.

Double Patenting:

The final Office Action *provisionally* rejects claims 1-25 on the grounds of non-statutory obviousness-type double patenting in view of claims 1, 2, 4-9, 11 and 12-17 of co-pending Application No. 10/731,551 in combination with the teachings of U.S. Patent No. 5,824,021 to Rise ("Rise"). Because this is a provisional rejection, Applicant declines to take any position at this time on the question of whether claims 1-25, as they may evolve during prosecution of this application, relate to the claims of Application No. 10/731,551 in view of Rise. Should Application No. 10/731,551 issue prior to the present application, Applicant reserves the right to then revisit the relationship, if any, between the claims of the two applications and to file a terminal disclaimer as to Application No. 10/731,551 in this application, if needed.

Prior Art:

The recent Office Action rejected claims 1-12, 15 and 17-25 as unpatentable under 35 U.S.C. § 103(a) over the combined teachings of U.S. Patent No. 6,058,331 to King ("King");

"Modification of Blood Flow to the Extremities by Electrical Stimulation of the Nervous System," by Dooley and Kasprak ("Dooley"); and U.S. Patent No. 5,193,540 to Schulman ("Schulman"). For at least the following reasons, this rejection is respectfully traversed.

Claim 1 recites:

> A method for treating a patient with peripheral vascular disease (PVD) or angina, comprising:
>
> providing a miniature leadless implantable stimulator with at least one electrode and with a size and shape suitable for placement entirely within the spinal column;
>
> *implanting the stimulator within said spinal column* and adjacent to at least one tissue influencing blood circulation, which tissue is at least one of the spinal roots;
>
> providing operating power to the stimulator;
>
> using an external appliance to transmit stimulation parameters to the stimulator;
>
> receiving the stimulation parameters at the stimulator;
>
> generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator;
>
> delivering stimulation pulses via the stimulator to the at least one of the spinal roots influencing blood circulation as a treatment for PVD or angina.

(Emphasis added).

The recent Office Action concedes that King and Dooley fail to teach or suggest providing a stimulator that is "suitable for placement entirely within the spinal column." (Action of 11/15/06, p. 6). Consequently, the Action cites to Schulman.

Regardless of what Schulman may teach about stimulator hardware, Applicant has previously pointed out that Schulman does not teach or suggest implanting a stimulator within a spinal column to treat PVD or angina. There is no teaching or suggestion in any of the prior art references of record of a *method* of implanting a stimulator within a patient's spinal column to treat PVD or angina.

In response to this argument, the final Office Action argues that, "[w]hile Schulman does not teach placing the microstimulator in the spinal column, it is of a size and shape suitable for placement in the spinal column." (Action of 11/15/06, p. 2). However, the Schulman reference does not ever state that the microstimulator disclosed is of a size and shape suitable for placement in the spinal column.

Moreover, even if we assume for the sake of argument that the Schulman microstimulator is, as the Office Action alleges, of a size and shape suitable for placement in the spinal column, that does not, by itself, teach or suggest the claimed method in which a stimulator is *actually* placed in the spinal column to treat PVD or angina. There is no teaching or suggestion in any of the prior art references of record of implanting a stimulator within a patient's spinal column to treat PVD or angina. Therefore, the final Office Action has accordingly failed to show on the record that one of skill in the art would have been taught Applicant's method by the prior art of record.

To the contrary, King teaches away from the claimed invention in this regard by expressly teaching that only a lead, not the implantable stimulator, is placed in the spinal column. (King, col. 5, lines 2-10). The final Office Action responds to this point by arguing that "[n]owhere does King explicitly state that a stimulator should not be placed in the spinal column." (Action of 11/15/06, p. 2). The fact that King does not explicitly state that a stimulator should not be placed in the spinal column does not mean that King teaches the converse, i.e., to place a stimulator in the spinal column. Such reasoning is equivalent to stating that King does not "explicitly state" that pigs can't fly. Therefore, King teaches that pigs can fly. Obviously this is erroneous reasoning.

Moreover, the fact that King does not explicitly state that a stimulator should not be placed in the spinal column does not change the fact that King *does* expressly teach one of skill in the art to place only a lead, not a simulator, in the spinal column. A reference is considered for what it actually teaches. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.* 776 F.2d 281, 227 U.S.P.Q. 657 (Fed. Cir. 1985).

In sum, none of the applied references, Schulman included, teach or suggest "implanting the stimulator *within said spinal column* and adjacent to at least one tissue influencing blood circulation, which tissue is at least one of the spinal roots" as a treatment for PVD or angina. (Emphasis added). "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least these reasons, the rejection of claim 1 and its dependent claims should be reconsidered and withdrawn.

Independent claim 12 recites:

> A method for treating a patient with angina, comprising:
> providing a miniature implantable stimulator with at least one electrode and with a size and shape suitable for placement of the entire stimulator within the spinal column;
> implanting the stimulator adjacent to at least one tissue influencing blood circulation, which tissue is at least one of the spinal roots;
> providing operating power to the stimulator;
> using an external appliance to transmit stimulation parameters to the stimulator;
> receiving the stimulation parameters at the stimulator;
> generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator;
> delivering stimulation pulses via the stimulator to the at least one of the spinal roots influencing blood circulation as a treatment for said angina.

Applicant notes that claim 12 recites a method for treating angina including "delivering stimulation pulses via the stimulator to the at least one of the spinal roots influencing blood circulation as a treatment for said angina."

Within the combination of cited prior art references, the final Office Action cites to and relies on Dooley as teaching a stimulator that provides stimulation at the C-6 dorsal roots. In this respect, Dooley teaches that "one patient had electrical stimulators implanted over the C-6 dorsal roots *for small artery disease of the upper extremities*." (Dooley, abstract) (emphasis added). Thus, Dooley teaches stimulating specific dorsal roots for treating artery disease of the upper extremities. Dooley does not, however, teach or suggest the claimed method including "delivering stimulation pulses via the stimulator to the at least one of the spinal roots influencing blood circulation *as a treatment for said angina*." (Emphasis added).

The final Office Action has failed to cite any prior art reference or combination thereof that teaches or suggests "delivering stimulation pulses via the stimulator to the at least one of the spinal roots influencing blood circulation *as a treatment for said angina*." (Emphasis added).

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least these reasons, the rejection of claim 12 and its dependent claims should be reconsidered and withdrawn.

Dependent claim 24 recites "wherein said at least one sensed condition comprises any change in dorsal column activity as an indicator of PVD." In this regard, the final Office Action cites to King at col. 6, lines 51-53. (Action of 11/15/06, p. 8).

This portion of King, in its entirety, states "[i]nternal sensor 40 may be a sensory recording electrode *for monitoring sensory signals that are caused by motion*. It may be located at the dorsal roots or peripheral nerves." (King, col. 6, lines 51-53) (emphasis added). Thus, King teaches monitoring sensory signals that are caused by motion via a recording electrode located at the dorsal roots.

King does not teach or suggest sensing "any change in dorsal column activity as an indicator of PVD." Consequently, the cited prior art combination fails to teach or suggest the method of claim 24, and the rejection of claim 24 should be reconsidered and withdrawn.

Claim 25 recites "delivering stimulation pulses to the cervical dorsal roots or cervical ventral roots as a treatment for angina." In this regard, the final Office Action cites to King at col. 5, lines 15-30. (Action of 11/15/06, p. 8).

The only mention in this portion of King of the cervical portion of the spinal column is as follows. "To control the blood flow to the hands, the electrodes may be placed epidurally at spinal vertebral levels C4-C8." (King, col. 5, lines 23-24). Thus, King, as cited in the final Office Action, teaches controlling blood flow *to the hands* by placing electrodes at the C4-C8 vertebrae.

King does not teach or suggest the claimed method of "delivering stimulation pulses to the cervical dorsal roots or cervical ventral roots *as a treatment for angina*." (Emphasis added). Consequently, the cited prior art combination fails to teach or suggest the method of claim 25, and the rejection of claim 25 should be reconsidered and withdrawn.

Claims 21-23 recite the following subject matter: "delivering excitatory stimulation pulses with a frequency of less than 100 Hz as a treatment for angina" (Claim 21); "wherein said stimulation pulses are delivered with a frequency of less than 100 Hz." (Claim 22); and "wherein said stimulation pulses are delivered with an amplitude of less than about 15 mA" (Claim 23).

The final Office Action improperly dismisses these claims with the statement that "discovering an optimum value or range for a result effective variable involves only routine skill in the art." (Action of 11/15/06, p. 8). This, however, does not apply to claims 21-23.

Applicant's specification makes clear that "different parameters may have different effects on different tissue." (Applicant's specification, paragraph 0051).

> Therefore, stimulation and control parameters may be chosen to target specific neural or other cell populations and/or to exclude others, or to increase activity in specific neural or other cell populations and/or to decrease activity in others. For example, relatively low frequency neurostimulation (i.e., less than about 50 100 Hz) may have an excitatory effect on surrounding neural tissue, leading to increased neural activity ("excitatory stimulation"), whereas relatively high frequency neurostimulation (i.e., greater than about 50-100 Hz) may have an inhibitory effect, leading to decreased neural activity ("inhibitory stimulation"). As another example, relatively low levels of stimulation current (typically less than about 15 mA, but dependent on the distance between electrodes and nerve fibers) are likely to recruit only relatively large diameter fibers (e.g., A-α and/or A-β fibers), while nociceptive fibers are typically relatively small diameter fibers (e.g., A-δ and/or C fibers).

(*Id.*).

This concept that "stimulation and control parameters may be chosen to target specific neural or other cell populations and/or to exclude others, or to increase activity in specific neural or other cell populations and/or to decrease activity in others" is not taught or suggested in any of the cited prior art references. Consequently, the subject matter of claims 21-23 achieves a specific beneficial result that is not taught or suggested by the prior art of record. These claims, therefore, cannot be dismissed as the mere optimization of parameters within the teaching of the

prior art. MPEP § 2144.05 ("A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)"). Consequently, the rejection of claims 21-23 should be reconsidered and withdrawn.

Claims 5, 6, 13, 14 and 16 were rejected as unpatentable under 35 U.S.C. § 103(a) over the combination of King, Dooley and Schulman in further combination with Rise. This rejection is respectfully traversed for at least the same reasons given above regarding claims 1 and 12.

Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper, that have not been authorized elsewhere, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

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